



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,329	01/29/2004	Sean D. Monahan	Mirus.041.01	6227
25032	7590 01/12/2006		EXAMINER	
MIRUS CORPORATION			VANIK, DAVID L	
505 SOUTH R				
MADISON, WI 53719			ART UNIT	PAPER NUMBER
			1615	
		DATE MAILED: 01/12/2006		

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)			
	10/767,329	MONAHAN ET AL.			
Office Action Summary	Examiner	Art Unit			
	David L. Vanik	1615			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
1) Responsive to communication(s) filed on 13 Oc	ctober 2005.				
2a)⊠ This action is <b>FINAL</b> . 2b)☐ This					
3) Since this application is in condition for allowan	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is				
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims					
4)⊠ Claim(s) <u>1-8 and 21-24</u> is/are pending in the application.					
4a) Of the above claim(s) is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.					
6)⊠ Claim(s) <u>1-8, 21-24</u> is/are rejected.					
7) Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction and/or	election requirement.				
Application Papers					
9)☐ The specification is objected to by the Examiner	<b>1.</b>				
10) The drawing(s) filed on is/are: a) □ acce	epted or b) $\square$ objected to by the E	Examiner.			
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).					
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
Priority under 35 U.S.C. § 119					
<ul> <li>12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) ☐ All b) ☐ Some * c) ☐ None of:</li> <li>1. ☐ Certified copies of the priority documents have been received.</li> </ul>					
2. Certified copies of the priority documents have been received in Application No					
3. Copies of the certified copies of the priority documents have been received in this National Stage					
application from the International Bureau (PCT Rule 17.2(a)).					
* See the attached detailed Office action for a list of the certified copies not received.					
Attachment(s)					
1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)					
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 5) Notice of Informal Patent Application (PTO-152)					
Paper No(s)/Mail Date 6)  Other:					

Application/Control Number: 10/767,329 Page 2

**Art Unit: 1615** 

## **DETAILED ACTION**

Receipt is acknowledged of the Applicant's Remarks and Amended Claims filed on 10/13/2005.

As a result of Applicant's amended claims, the *35 USC §102* rejections over EP 0335133 A2 ('133) are hereby **withdrawn**. Additionally, as a result of Applicant's amended claims, the *35 USC §103* rejections over Zelphati et al (Intracellular Delivery of Proteins with a New Lipid-mediated Delivery System) in view of Maa et al (Biopharmaceutical powders: particle formation and formulation considerations) as well as US 2003/0054007 ('007) in view of Maa et al (Biopharmaceutical powders: particle formation and formulation considerations) are hereby **withdrawn**.

## **NEW REJECTIONS:**

The following is a list of new rejections:

## Claim Rejections - 35 USC § 112

Claims 1-8, 21-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

Art Unit: 1615

had possession of the claimed invention. The instant claims 1-8, 21-24 have been amended to encompass the limitation of "polypeptide-detergent." This term is not set forth in the instant specification and, as such, is considered to be new matter. Moreover, after electronically searching the instant specification, the only mention of "detergent" is in the definitions portion of the text (See pages 13-14 of the instant specification). Since, the instant application is concerned with polypeptide-surfactant complexes and the amended claims read on a more narrow "polypeptide-detergent" limitation, the newly amended claims fail to comply with the written description requirement.

Page 3

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Application/Control Number: 10/767,329

**Art Unit: 1615** 

Correspondence

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to David L. Vanik whose telephone number is (571) 272-

3104. The examiner can normally be reached on Monday-Friday 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number

for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

David Vanik, Ph.D.

Art Unit 1615

Page 4

1/9/2006